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Proposed Maximum Residue Limit PMRL2013-112

Thiamethoxam

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various fruits and vegetables to the product label of Actara® 25WG Insecticide, containing technical grade thiamethoxam, is acceptable. The specific uses approved in Canada are detailed on the label of Actara® 25WG Insecticide, *Pest Control Products Act* Registration Number 28408.

The evaluation of these thiamethoxam applications indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for thiamethoxam is being conducted via this document (see Next Steps, the last section of this document). Details regarding the registration for Root Vegetables (except sugar beets; Crop Subgroup 1B) and Tuberous and Corm Vegetables (Crop Subgroup 1C) can be found in the corresponding Evaluation Report available in the Pesticides and Pest Management section of Health Canada's website, under Public Registry, Pesticide Product Information Database.[1] A summary of the field trial data used to support the remaining proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace or be added to the MRLs already established for thiamethoxam, are as follows.

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1 The relevant report can be accessed by selecting Applications/Minor Use/Historical and requesting the Evaluation Report found under Application Number 2012-0699.

Table 1 Proposed Maximum Residue Limits for Thiamethoxam

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Thiamethoxam	3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine, including the metabolite (*E*)-*N*-[(2-chloro-5-thiazolyl)methyl]-*N'*-methyl-*N''*-nitroguanidine	0.8	Cassava leaves, tanier leaves, and taro leaves
		0.6[2]	Bell peppers
		0.5	Caneberry Subgroup (Crop Subgroup 13-07A)[3], black cherries, capulins, chokecherries, Nanking cherries
		0.3	Cranberries
		0.25	African eggplants, bush tomatoes, coconas, currant tomatoes, garden huckleberries, Goji berries, martynias, naranjillas, okras, pea eggplants, roselles, Scarlett eggplants, sunberries, and tree tomatoes
		0.02	Arracacha, arrowroot, Chinese artichokes, Jerusalem artichokes, edible canna, cassava roots, chayote roots, chufa, taro corms, ginger roots, lerens, sweet potato roots, tanier corms, turmeric roots, yam bean roots, and true yam tubers

[1] ppm = parts per million

[2] Proposed to replace the established MRL of 0.25 ppm for residues of thiamethoxam in/on bell peppers (EMRL2012-30).

[3] The MRL for the Caneberry Subgroup is proposed to replace the currently established 0.35 ppm MRL for crops in this subgroup.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for

established MRLs, regulated under the *Pest Control Products Act* (, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for thiamethoxam in Canada with corresponding American tolerances and Codex MRLs.[2] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Cassava leaves, tanier leaves, and taro leaves	0.8	Not established	Not established
Bell peppers	0.6	0.25 (Vegetable, fruiting, group 8	0.7 (Fruiting vegetables other than cucurbits)
Caneberry Subgroup (Crop Subgroup 13-07A)	0.5[1]	0.35 (Caneberry subgroup 13-07A)	0.5 (Berries and other small fruits)
Black cherries, capulins, chokecherries, Nanking cherries	0.5	0.5 (Fruit, stone, group 12)	1 (Stone fruits)
African eggplants, bush tomatoes, coconas, currant tomatoes, garden huckleberries, Goji berries, martynias, naranjillas, okras, pea eggplants, roselles, Scarlett eggplants, sunberries, and tree tomatoes	0.25	0.25 (Vegetable, fruiting, group 8)	0.7 (Fruiting vegetables other than cucurbits)

[2] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Cranberries	0.3	0.02	0.5 (Berries and other small fruits)
Arracacha, arrowroot, Chinese artichokes, Jerusalem artichokes, edible canna, cassava roots, chayote roots, chufa, taro corms, ginger roots, lerens, sweet potato roots, tanier corms, turmeric roots, yam bean roots, and true yam tubers	0.02	0.02 (Vegetable, tuberous and corm, except potato, subgroup 1D)	0.3 (Root and tuber vegetables)

[1] The MRL is proposed to replace the currently established 0.35 ppm MRL for crops in this subgroup.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for thiamethoxam up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Actara® 25WG Insecticide on various fruits and vegetables. In addition, residue data on file were re-assessed within the framework of the current petition.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for thiamethoxam in/on caneberries was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. The recommendation for a maximum residue limit (MRL) for thiamethoxam in/on bell peppers was based upon the submitted greenhouse trial data, and the guidance provided in the OECD MRL Calculator. The recommendation for a MRL for thiamethoxam in/on African eggplants, bush tomatoes, coconas, currant tomatoes, garden huckleberries, Goji berries, martynias, naranjillas, okras, pea eggplants, roselles, Scarlett eggplants, sunberries, and tree tomatoes was based upon the field trial data, guidance provided in PRO2005-04, *Guidance for Setting Pesticide Maximum Residue Limits Based on Field Trial Data*, and the North American Free Trade Agreement calculator as the MRL statistical methodology.

Based on the maximum residue observed in crops treated at exaggerated rates and harvested at the appropriate PHI, it was determined that residues of thiamethoxam and the metabolite CGA-322704 in sweet cherries and tart cherries would be covered under the maximum residue limit (MRL) of 0.5 ppm currently established for this commodity. Sweet cherries and tart cherries are the representative crops for Crop Subgroup 12-09A (Cherry Subgroup). As such, the MRL of 0.5 ppm for sweet cherries and tart cherries will be extended to the remaining crops in this subgroup (i.e. black cherries, capulins, chokecherries, and Nanking cherries).

Based on the maximum residue observed in strawberries treated at exaggerated rates and harvested at the appropriate preharvest interval, it was determined that residues of thiamethoxam and the metabolite CGA-322704 in lowbush blueberries, bearberries, bilberries, cloudberries, lingonberries, muntries, partridgeberries, and strawberries would be covered under the MRL of 0.3 ppm currently established for these commodities. Strawberry is the representative crop for Crop Subgroup 13-07G (Low growing berry Subgroup). As such, the MRL of 0.3 ppm will be extended to cranberries, which are also included in this subgroup.

Table A1 summarizes the residue data used to calculate the proposed MRLs.

Table A1 Summary of Field Trial Data Used to Support Maximum Residue Limits

Commodity	Application Method/ Total Application Rate (g a.i./ha)	Preharvest Interval (days)	Residues (ppm)	
			Min	Max
Raspberry	Foliar/ 139.1–147.6	2–4	<0.107	<0.284
Tomato	Postemergent foliar spray/ 123–198	0–1	<0.02	0.16
Bell Pepper (field grown)	Postemergent foliar spray/ 121–198	0–1	<0.02	<0.19
Non-Bell Pepper (field grown)	Postemergent foliar spray/ 123–198	0–1	<0.04	0.24
Sweet Bell Peppers (greenhouse grown)	Foliar/ 200	0–1	<0.09	<0.33
Sweet and tart cherries	Foliar/ 192.8	13–15	0.13	0.30
Strawberries	Foliar/ 222	3	<0.02	<0.27

Following the review of all available data, MRLs as indicated in Table 1 are recommended to cover residues of thiamethoxam in various fruits and vegetables. Residues of thiamethoxam in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.